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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/141,017	10/26/1993	EUGENE P. GOLDBERG		7268

7590 09/30/2009
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GAINSVILLE, FL 32611-2066

EXAMINER

FISHER, ABIGAIL L

ART UNIT	PAPER NUMBER
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1616

MAIL DATE	DELIVERY MODE
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09/30/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary**Application No.**

08/141,017

Applicant(s)

GOLDBERG ET AL.

Examiner

ABIGAIL FISHER

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date: _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Receipt of Amendments/Remarks filed on June 9 2009 is acknowledged. Claim 2 stands cancelled. Claims 1 and 5 were amended. Claims 1, 3-7 are pending.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 1, 6-7 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is **withdrawn** as applicants' arguments indicate that any polypeptide or polysaccharide can be utilized as long as it possess the molecular weight requirement.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 1 and 3-7 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter

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which applicant regards as the invention is **withdrawn** in light of Applicants'

amendments filed on June 9 2009.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 4 and 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lambert (US Patent No. 4585666) in view of Schwartz et al. (US Patent No. 4589873).

Applicant Claims

Applicant claims a method of protecting tissue and reducing tissue damage in surgery comprising providing surfaces that are involved in said surgery with a wet coating of an aqueous solution of polymeric material prior to manipulation of said tissue during said surgery. The polymeric material is carboxymethylcellulose, polyvinylpyrrolidone, polypeptide, polysaccharide excluding hyaluronic acid having a molecular weight above 1,500,000 and chondroitin sulfate, salt, complex, or mixture thereof. The polymeric material has a molecular weight of about 50,000 D or above and the concentration in the aqueous solution of said polymer is in the range from about 0.01 to 15% by weight.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Lambert is directed to a coating for a polymer surface. The hydrophilic coating has a low coefficient of friction and can be utilized to coat medical articles (column 1, lines 8-10). Examples 1 and 2 are directed to coating a urinary catheter. The catheter is dipped in a PVP solution and then cured above a bowl filled with water. It is disclosed that the presence of water during the curing process is to help bind the hydrophilic PVP (column 2, lines 53-67). The PVP is utilized in a solution from 0.5 to 10% (column 2, lines 49-51). The molecular weight of the PVP is from 10^4 to 10^7 (column 2, lines 41-42). Other surfaces that may be coated include latex rubber (column 1, line 56).

**Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)**

Lambert et al. does not specify that the PVP can be dissolved in water.

However, this deficiency is cured by Schwartz et al.

Schwartz et al. indicates that the hydrophilic polymer PVP is water soluble (column 1, lines 49-50).

***Finding of Prima Facie Obviousness Rational and Motivation*
(MPEP §2142-2143)**

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Lambert et al. and Schwartz et al. and dissolve the PVP in water. One of ordinary skill in the art would have been motivated to utilize water as the solvent which to dissolve PVP because Schwartz et al. teach that PVP is water soluble. Additionally, since water is utilized in the curing process of Lambert et al., utilizing water as the solvent which to dissolve PVP would eliminate the step of having to remove a different solvent and one could go immediately from coating to curing.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Regarding claim 6, applicant claims broad surgical classes. Schwartz et al. teach that the PVP solution can be utilized to coat latex rubber, such as rubber gloves.

Gloves would be utilized in every type of surgery as they are a necessary component of a surgical procedure.

Response to Arguments

Applicants argue that (1) claim 1 requires that the polymeric material exclude (i) hyaluronic acid having a molecular weight about 1,500,000 and above and (ii) chondroitin sulfate, salt, complex or mixture thereof. It is argued that office action does not address this limitation or show where this limitation is disclosed. Applicants argue that (2) claim 1 further requires that the concentration of the polymer in the aqueous solution be in the range from about 0.01% to about 15% by weight and that the molecular weight of the polymer and concentration have values such that the aqueous solution is capable of providing wet coatings on said surfaces involved in surgery. The office action fails to show how the combined teachings of Lambert and Schwartz et al. would leave a person skilled in the art to arrive at the claimed concentration range to achieve a wet coating.

Applicants' arguments filed June 9 2009 have been fully considered but they are not persuasive.

Regarding applicants' first argument, the compositions of Lambert comprise PVP and only PVP as the polymer. Therefore, it would necessarily meet the limitations of claim 1 that requires that the polymeric material exclude (i) hyaluronic acid having a molecular weight about 1,500,000 and above and (ii) chondroitin sulfate, salt, complex or mixture thereof.

Regarding applicants' second argument, the amount of PVP taught in Lambert ranges from 0.5 to 10%. This amount falls within the instantly claimed concentration. The molecular weight also reads on the instantly claimed molecular weight as there is no upper limit claimed. Lambert teaches the same claimed polymer in the same claimed amount. Therefore, teachings of Lambert meet the claimed limitations of the instant application.

Therefore, the rejection is maintained since applicant has not provided any persuasive arguments to overcome the rejection.

Claims 1 and 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soll et al. (US Patent No. 4486416) as evidenced by Gough (US Patent No. 4335105).

Applicant Claims

Applicant claims a method of protecting tissue and reducing tissue damage in surgery comprising providing surfaces that are involved in said surgery with a wet coating of an aqueous solution of polymeric material prior to manipulation of said tissue during said surgery. The polymeric material is carboxymethylcellulose, polyvinylpyrrolidone, polypeptide, polysaccharide excluding hyaluronic acid having a molecular weight above 1,500,000 and chondroitin sulfate, salt, complex, or mixture thereof. The polymeric material has a molecular weight of about 50,000 D or above and the concentration in the aqueous solution of said polymer is in the range from about 0.01 to 15% by weight.

Determination of the Scope and Content of the Prior Art

(MPEP §2141.01)

Soll et al. is directed to protection of human and animal cells subject to exposure to trauma. It is taught that macromolecules employed in the protection of corneas prior to surgery include bovine serum albumin (a protein which is necessarily a polypeptide), human gamma globulin, hyaluronic acid, and polyvinylpyrrolidone (column 1, lines 24-31). Tables 2 and 3 show the use of chondroitin sulphate, bovine serum albumin, hyaluronic acid and polyvinylpyrrolidone were tested for their protection of corneas during implantation surgery. It is taught that solutions were made with normal saline (column 7, lines 31-42). The amount of bovine serum albumin utilized was 22%, hyaluronic acid was 10% and polyvinylpyrrolidone was 7% (column 9, lines 1-11). It is taught that the molecular weight of HEALON is greater than 1,000,000 (column 4, lines 39-41).

**Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)**

Soll et al. does not explicitly teach utilizing the polyvinylpyrrolidone, bovine serum albumin, or hyaluronic acid in the claimed method. However, Soll et al. do teach that they are known in the art to be employed in the protection of corneas prior to surgery and that they do provide some degree of protection.

***Finding of Prima Facie Obviousness Rationale and Motivation*
(MPEP §2142-2143)**

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to utilize bovine serum albumin or hyaluronic acid in a method of protecting corneas prior to surgery. One of ordinary skill in the art would have been

motivated to utilize these polymers in a method of protecting corneas it is taught by Soll et al. that these polymers are known in the art to be utilized for protecting corneas prior to surgery. One of ordinary skill in the art would have a reasonable expectation of success as Soll et al. teach that bovine serum albumin and hyaluronic acid provide some degree of protection of corneas prior to surgery.

Regarding the molecular weight of hyaluronic acid, the instant claims recite a molecular weight greater than 50,000 but the hyaluronic acid needs to be less than 1,500,000. Soll et al. teach the molecular weight of the hyaluronic acid is greater than 1,000,000. Therefore, the molecular weight would meet the instant limitations as it includes values below 1,500,000.

Regarding the molecular weight of bovine serum albumin, as evidenced by Gough the molecular weight of bovine serum albumin is 66,000 (column 8, lines 58-59).

Regarding the claimed types of surgery, corneal surgery would broadly fall under reconstructive, prosthetic, plastic or muscle surgery.

Regarding the claimed amount of bovine serum albumin, 22% is about 15.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 4 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soll et al. as evidenced by Gough and in view of Lambert.

Applicant Claims

Applicant claims a method of protecting tissue and reducing tissue damage in surgery comprising providing surfaces that are involved in said surgery with a wet coating of an aqueous solution of polymeric material prior to manipulation of said tissue during said surgery. The polymeric material is carboxymethylcellulose, polyvinylpyrrolidone, polypeptide, polysaccharide excluding hyaluronic acid having a molecular weight above 1,500,000 and chondroitin sulfate, salt, complex, or mixture thereof. The polymeric material has a molecular weight of about 50,000 D or above and the concentration in the aqueous solution of said polymer is in the range from about 0.01 to 15% by weight.

Specifically claimed polymer is polyvinylpyrrolidone. One specific surface claimed with both surgical device and tissues.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Soll et al. are set forth above. Specifically, Soll et al. teach that polyvinylpyrrolidone, bovine serum albumin and hyaluronic acid are known in the art to be employed in the protection of corneas prior to surgery and that they all provide some degree of protection.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Soll et al. do not specify the molecular weight of polyvinylpyrrolidone or teach coating both surgical devices and tissues. However, these deficiencies are cured by Lambert.

The teachings of Lambert are set forth above. Specifically, Lambert teach utilizing a hydrophilic coating to produce low coefficient friction on medical devices. Specific medical devices include latex gloves. The molecular weight of polyvinylpyrrolidone taught is from 10^4 to 10^7 .

***Finding of Prima Facie Obviousness Rationale and Motivation
(MPEP §2142-2143)***

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Soll et al. and Lambert and utilize polyvinylpyrrolidone with a molecular weight in the range of 10^4 to 10^7 . One of ordinary skill in the art would have been motivated to utilize this molecular weight of polyvinylpyrrolidone as it is taught as a suitable molecular weight to form a hydrophilic coating and Soll et al. teach that polyvinylpyrrolidone can be utilized to protect corneas prior to surgery.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Soll et al. and Lambert and utilize coatings on both tissues and surgical devices. One of ordinary skill in the art would have been motivated to coat both the tissues and surgical devices prior to corneal surgery as Soll et al. teach coatings comprising bovine serum albumin, hyaluronic acid and polyvinylpyrrolidone can be utilized to coat corneas prior to surgery and Lambert teach coating medical devices including latex gloves which are utilized in virtually every

surgery reduce friction during surgery. Therefore, it would have been obvious to one of ordinary skill in the art to utilize coatings in order to protect tissues during surgery. One of ordinary skill in the art would expect that coating both the tissues and the medical devices would have an added effect in protecting the tissues from damage.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicants argue that Soll et al. require chondroitin sulfate and teach away from the claimed invention. Applicants argue that claim 1 requires that the polymeric material exclude (i) hyaluronic acid having a molecular weight about 1,500,000 and above and (ii) chondroitin sulfate, salt, complex or mixture thereof. The office action relies on a teaching of Soll et al. which shows that sodium hyaluronate polymer has a molecular weight of 1,000,000. While this may disclose that Soll et al. disclose hyaluronic acid that meets the claim limitation, the wet coating of the claim excludes chondroitin sulfate, a key ingredient in Soll's composition. The compositions in Table 2 compositions without chondroitin sulfate showed a significantly higher number of cornea's damage. A composition comprising only chondroitin sulfate and bovine serum albumin alone there was a higher percentage of damage. Therefore, this leads a person skilled in the art away from the instant invention.

Applicants' arguments filed June 9 2009 have been fully considered but they are not persuasive.

Firstly, it appears applicants have misconstrued some of the teachings in Soll et al. Soll et al. teach four separate IOL coatings. One solution containing chondroitin sulfate, one containing bovine serum albumin, one containing hyaluronic acid, and one containing polyvinylpyrrolidone. While, Soll et al. does teach that chondroitin sulfate performs better than the other formulations. All four formulations provided some degree of protection of the cornea. Therefore, while Soll et al. may teach that chondroitin sulfate is preferable and the most effective, it is not a teaching away from utilizing the other three solutions. One of ordinary skill in the art would just expect that these other compositions would work less effectively than chondroitin sulfate "Disclosed examples and preferred embodiments do not constitute a teaching away from the broader disclosure or non-preferred embodiment." *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). Clearly, the other three polymeric solutions work albeit to a lesser degree. Furthermore, the other three polymeric solutions do not contain chondroitin sulfate.

Therefore, the rejection is maintained since applicant has not provided any persuasive arguments to overcome the rejection.

Claims 1, 3, 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schechter (US Patent No. 4510145) in view of Chiou (US Patent No. 4564821).

Applicant Claims

Applicant claims a method of protecting tissue and reducing tissue damage in surgery comprising providing surfaces that are involved in said surgery with a wet coating of an aqueous solution of polymeric material prior to manipulation of said tissue during said surgery. The polymeric material is carboxymethylcellulose, polyvinylpyrrolidone, polypeptide, polysaccharide excluding hyaluronic acid having a molecular weight above 1,500,000 and chondroitin sulfate, salt, complex, or mixture thereof. The polymeric material has a molecular weight of about 50,000 D or above and the concentration in the aqueous solution of said polymer is in the range from about 0.01 to 15% by weight.

Specifically claimed polymer is carboxymethylcellulose.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Schacher is directed to a method for controlling the contraction of ophthalmic wounds or incisions (abstract). The composition comprises a smooth muscle relaxant and thickeners are added in order to adjust the viscosity. Suitable viscosity building agents include gums or cellulosic polymer such as carboxymethylcellulose. These polymers are present in an amount from 0.001 to about 1% (column 3, lines 5-20). It is taught that application of the composition can be utilized to control the contraction of ophthalmic wounds or incisions and is particularly useful in preventing the contraction of incision in anterior radial keratotomy (column 1, lines 50-63). The compositions can be applied topically via solution in an ophthalmic vehicle including aqueous solutions (column 2, lines 23-39).

**Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)**

Schacher does not specify the molecular weight of the carboxymethyl cellulose. However, this deficiency is cured by Chiou.

Chiou is directed to ophthalmic compositions. Molecular weight of carboxymethylcellulose taught for being suitable in ophthalmic solutions are from 10,000 to 1,000,000 (column 7, lines 1-19).

***Finding of Prima Facie Obviousness Rationale and Motivation*
(MPEP §2142-2143)**

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Schacher and Chiou and utilize carboxymethylcellulose in ophthalmic solutions to be utilized to control the contraction of ophthalmic wounds or incisions. One of ordinary skill in the art would have been motivated to utilize carboxymethylcellulose as it is a polymer specifically taught by Schacher as being suitable. It would have been obvious to one of ordinary skill in the art to try any of the specifically taught polymers as a person with ordinary skill has good reason to pursue known options within his or her technical grasp. **Note: MPEP 2141 [R-6] KSR International CO. v. Teleflex Inc.** 82 USPQ 2d 1385 (Supreme Court 2007).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Schacher and Chiou and utilize carboxymethylcellulose with a molecular weight range from 10,000 to 1,000,000. One of ordinary skill in the art would have been motivated to utilize this weight range as it is a range specifically taught as suitable for ophthalmic solutions. Furthermore, it would

have been obvious to one of ordinary skill in the art to vary the molecular weight in order to optimize the viscosity of the solution. It would have been obvious to one of ordinary skill in the art at the time of the invention to engage in routine experimentation to determine optimal or workable ranges that produce expected results. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F. 2d 454, 105 USPQ 233 (CCPA 1955).

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicants argue that (1) claim 1 requires that the polymeric material exclude (i) hyaluronic acid having a molecular weight about 1,500,000 and above and (ii) chondroitin sulfate, salt, complex or mixture thereof. It is argued that office action does not address this limitation or show where this limitation is disclosed. Applicants argue that (2) claim 1 further requires that the concentration of the polymer in the aqueous solution be in the range from about 0.01% to about 15% by weight and that the molecular weight of the polymer and concentration have values such that the aqueous solution is capable of providing wet coatings on said surfaces involved in surgery. There is no disclosure in Schechter that the carboxymethylcellulose has the claimed molecular

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weight. The office action fails to show how the combined teachings of Schechter would leave a person skilled in the art to arrive at the claimed concentration range to achieve a wet coating.

Applicants' arguments filed June 9 2009 have been fully considered but they are not persuasive.

Regarding applicants' first argument, the compositions Schechter comprise carboxymethylcellulose and hyaluronic acid and chondroitin sulfate are not taught or contemplated to be added to the compositions. Therefore, their exclusion would necessarily be taught by the teachings of Schechter.

Regarding applicants' second argument, the concentration of the solutions taught range from 0.001 to about 1%, which overlaps that instantly claimed. While Schechter is silent as to the molecular weight of the carboxymethylcellulose that is why Chiou is relied upon. Chiou is directed to ophthalmic compositions (which is what the compositions of Schechter are directed to). The molecular weight of the carboxymethylcellulose utilized in these types of solution ranges from 10,000 to 1,000,000. This amount overlaps that instantly claimed. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. **See MPEP 2144.05 [R-5]**. Therefore, applicants have not demonstrated how the instantly claimed concentrations and molecular weights are not obvious in view of the teachings of Schechter and Choiu.

Therefore, the rejection is maintained since applicant has not provided any persuasive arguments to overcome the rejection.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ABIGAIL FISHER whose telephone number is (571)270-3502. The examiner can normally be reached on M-Th 9am-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Abigail Fisher
Examiner
Art Unit 1616

AF

/Mina Haghighatian/
Primary Examiner, Art Unit 1616